



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Registration Division

11/07/2016

MEMORANDUM (Revised DER #2724-483)

Subject: Name of Pesticide Product: **Sandoz 9404 Spray**
EPA Reg. No. /File Symbol: 2724-483
DP Barcode: 435676
Decision No.: 520697
PC Code: 105402, 109701

From: Masih Hashim, Ph. D., Team Leader Toxicology *M Hashim*
Thru: John C. Redden, M.S., Senior Assessor
Chemistry, Inerts, and Toxicology Assessment Branch (CITAB)
Registration Division (7505C) *JCR*

To: Autumn Metzger/Laura Bacon- RM 04
Invertebrate and Vertebrate Branch 1
Registration Division (7505C)

Applicant: WELLMARK INTERNATIONAL
Schaumburg, IL 60173

FORMULATION FROM LABEL:

<u>Active Ingredients:</u>	<u>% by wt.</u>
S-Methoprene	0.09
Permethrin	0.50
<u>Inert Ingredient(s):</u>	<u>99.41</u>
Total: 100.00%	

ACTION REQUESTED/ BACKGROUND: The Risk Manager requests: A revision of label based on the new studies: dermal irritation, and dermal sensitization (MRID 500022 01-02)* replacing the old studies.

RECOMMENDATIONS: The new submitted tox studies* are acceptable, and have replaced the old ones. The new Signal Word is CAUTION.

The revised toxicity profile is as follows:

Acute oral toxicity	IV	cited	MRID 43446405
Acute dermal toxicity	III	cited	MRID 43446406
Acute inhalation study	IV	cited	MRID 43446410
Eye irritation study	IV	cited	MRID 43446408
Primary skin irritation	IV	acceptable	MRID 50002201*
Dermal sensitization	neg.	acceptable	MRID 50002202*

*(The two studies MRID 434464-07 and 09 have been replaced by 500022 01 and 02, respectively).

LABELING:

PRODUCT ID #: 002724-00483

PRODUCT NAME: Sandoz 9404 Spray

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Contains Petroleum Distillate.

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: May pose an aspiration pneumonia hazard. Contains petroleum distillate. The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations (optional- the PM may change this part).

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. User should remove PPE immediately after handling this product.

Wash outside of gloves before removing, and wash thoroughly and change into clean clothing, as soon as possible.

Revised data for 2724-483

CURRENT DATE: 11-6-2016 DP 435676				
TEST MATERIAL: actives S. Methoprene 0.114, Permethrin 0.598% Milky white emulsion				
Study / Species/ Laboratory/Study #/ Date	MRIDs	Results	Tox Cat	Core (
OPPTS 870-2500 Primary dermal irritation/ /rabbit/PSL/#40883/6-08-2015	50002201	Causes mild irritation PDII 1.4	IV	A
870-2600-OECD 429 (OECD 406) Dermal sensitization/g..pigs/PSL/ 40804/6-1-2015	50002202	At 24 hrs it was 0/20 48 hrs 0/20 animals Controls 0/10, 0/10	negative	A



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 8, 2010

MEMORANDUM:

Subject: EPA Reg. No.: 2724-483 Sandoz 9404 Spray
DP Barcode: 381163
Case No.: 2510

From: Jolene Trujillo, Biologist *Jolene E Trujillo*
Risk Management and Implementation Branch V (7508P)
Pesticide Re-evaluation Division *MTJ*

To: Maia Tatinclaux, CRM
Risk Management and Implementation Branch V (7508P)
Pesticide Re-evaluation Division

Applicant: Wellmark International
1501 E. Woodfield Rd., Suite 200 West
Schaumburg, IL 60173

FORMULATION FROM EPA Reg. No. 2724-483 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
(S)-Methoprene	0.09%
Permethrin	0.50%
<u>Other Ingredient(s):</u>	<u>99.41%</u>
Total	100.00%

Contains petroleum distillates

BACKGROUND: In the 8 month response to the Permethrin RED, the registrant has cited acute toxicity studies to support the reregistration of their product, EPA Reg. No. 2724-483. The MRID Nos. are as follows: 434464-05 (81-1), 434464-06 (81-2), 434464-10 (81-3), 434464-08 (81-4), 434464-07 (81-5), 434464-09 (81-6). The studies were conducted by Pharmco LSR and the test material used in each of the studies was EPA Reg. No. 2724-464.

RECOMMENDATIONS:

- The acute toxicity studies submitted are acceptable to support the reregistration of EPA Reg. No. 2724-483.

The acute toxicity profile for EPA Reg. No. 2724-483 is currently:

Acute Oral	IV	Acceptable (LD ₅₀ >5100 mg/kg)
Acute Dermal	III	Acceptable (LD ₅₀ >2100 mg/kg)
Acute Inhalation	IV	Acceptable
Primary Eye	IV	Acceptable
Primary Dermal	II	Acceptable
Skin Sensitization	Sensitizer	Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 2724-483 Sandoz 9404 Spray

INGREDIENT STATEMENT: Contains petroleum distillates.

SIGNAL WORD: WARNING

RESTRICTED USE CLASSIFICATION REQUIRED

Due to Primary Dermal Toxicity Category

CHILD RESISTANT PACKAGING REQUIRED

Due to Primary Dermal Toxicity Category

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Causes skin irritation. Do not get in on skin, in eyes, or clothing. Harmful if absorbed through skin. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with

plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Immediately call a poison control center or doctor. Do not induce vomiting unless told to by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center, doctor, or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN:

Contains petroleum distillate. Vomiting may cause aspiration pneumonia

DATA REVIEW FOR ACUTE ORAL TOXICITY (§81-1, 870.1100)

Product Manager: R. Gebkin/ 13
MRID No.: 434464-05

Reviewer: Jolene Trujillo
Study Completion Date: 10-14-94
Report No.: 94-0964

Testing Facility: Pharmco LSR
Author: Donna L. Blaszcak B.S. AALAS, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Manufacture Concentrate for 9309 Sandoz Water Based Fogger
Species: Sprague-Dawley derived albino rat

Conclusion:

1. **LD₅₀ (mg/kg):** > 5100 mg/kg

2. **Toxicity Category:** IV

Classification: Acceptable

Procedure (Deviations from §81-1): none

Results:

Dose mg/kg	(number deaths/number tested)		
	Males	Females	Combined
5100	0/5	0/5	0/10

DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1100)

Product Manager: R. Gebkin/ 13

MRID No.: 434464-06

Reviewer: Jolene Trujillo

Study Completion Date: 10-14-94

Report No.: 94-0964

Testing Facility: Pharmco LSR

Author: Donna L. Blaszcak B.S. AALAS, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Manufacture Concentrate for 9309 Sandoz Water Based Fogger

Species: New Zealand albino rabbit

Summary:

1. **LD₅₀ (mg/kg):** > 2100 mg/kg

2. **Toxicity Category:** III

Classification: Acceptable

Procedure (Deviations From §81-2): none

Results:

Reported Mortality

Dosage (mg/kg)	(number deaths/number tested)		
	Males	Females	Combined
2100	0/5	0/5	0/10

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: R. Gebkin/ 13
MRID No.: 434464-10

Reviewer: Jolene Trujillo
Study Completion Date: 10-14-94
Report No.: 94-5182

Testing Facility: Pharmco LSR
Author: Gary M. Hoffman BA DABT

Quality Assurance (40 CFR §160.12): Included

Test Material: Manufacture Concentrate for 9309 Sandoz Water Based Fogger
Species: Sprague-Dawley derived albino rat

Summary:

1. **LC₅₀ (mg/L):** > 2.7 mg/L

2. **MMAD:** 3.0 µm

GSD: 1.9

3. **Tox. Category:** IV

Classification: Acceptable

Procedure (Deviation From §81-3): none

Results: **Reported Mortality**

Exposure Concentration	(number deaths/number tested)		
	Males	Females	combined
2.7 mg/L	0/10	0/10	0/20

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: R. Gebkin/ 13
MRID No.: 434464-08

Reviewer: Jolene Trujillo
Study Completion Date: 10-14-94
Report No.: 94-0966

Testing Facility: Pharmco LSR

Author: Donna L. Blaszcak B.S. AALAS, LATG

Test Material: Manufacture Concentrate for 9309 Sandoz Water Based Fogger

Dosage: 0.1 mL

Species: New Zealand albino rabbit

Summary:

Toxicity Category: IV

Classification: Acceptable

Procedure (Deviations From §81-4): none

Results:

Observations	(number "positive"/number tested)			
	Hours			
	1	24	48	72
Corneal Opacity	0/6	0/6	0/6	0/6
Iris	0/6	0/6	0/6	0/6
Conjunctivae				
Redness	0/6	0/6	0/6	0/6
Chemosis	0/6	0/6	0/6	0/6
Discharge	0/6	0/6	0/6	0/6

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: R. Gebkin/ 13
MRID No.: 434464-07

Reviewer: Jolene Trujillo
Study Completion Date: 10-14-94
Report No.: 94-0955

Testing Facility: Pharmco LSR
Author: Donna L. Blaszcak B.S. AALAS, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Manufacture Concentrate for 9309 Sandoz Water Based Fogger

Dosage: 0.5 mL

Species: New Zealand albino rabbit

Summary:

- Toxicity Category:** II **PII = 2.0**
- Classification:** Acceptable

Procedure (Deviations From §81-5): none

Results:

Table 1							
Primary Dermal Irritation Study of Manufacturing Concentrate for 9309-Sandoz Water Based Fogger in Rabbits							
Individual Dermal Irritation Scores ^a							
Rabbit Pattern No. ^b :		1	2	3	4	5	6
Time Interval	Observations	2110F	2111M	2112F	2113M	2114F	2116F
Hours							
0.5	ER	2	2	2	2	2	2
	ED	1	1	0	1	0	0
	Other	-	-	-	-	-	-
24	ER	2	2	2	2	2	2
	ED	0	0	0	0	0	0
	Other	-	-	-	-	-	-
48	ER	2	1	1	2	2	2
	ED	0	0	0	0	0	0
	Other	-	-	-	-	-	-
72	ER	2	1	1	3	2	3
	ED	0	0	0	0	0	0
	Other	-	-	-	-	-	-

Table 1 (cont.)							
Primary Dermal Irritation Study of Manufacturing Concentrate for 9309-Sandoz Water Based Fogger in Rabbits							
Individual Dermal Irritation Scores (cont.) ^a							
Rabbit Pattern No. ^b :		1	2	3	4	5	6
Time Interval	Observations	2110F	2111M	2112F	2113M	2114F	2116F
Day							
7	ER	2	1	0	1	1	2
	ED	0	0	0	0	0	0
	Other	-	-	-	0	0	-
10	ER	0	1		1	1	1
	ED	0	0		0	0	0
	Other	-	-		0	0	0
14	ER		0		0	0	0
	ED		0		0	0	0
	Other		-		0	0	0

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: R. Gebkin/ 13
MRID No.: 434464-09

Reviewer: Jolene Trujillo
Study Completion Date: 10/1994
Report No.: 94-0944

Testing Facility: Pharmco LSR
Author: Donna L. Blaszcak B.S. AALAS, LATG

Quality Assurance (40 CFR §160.12): Included

Test Material: Manufacture Concentrate for 9309 Sandoz Water Based Fogger

Positive Control Material: DNCB

Species: Hartley albino guinea pig

Method: Buehler

Summary:

1. This Product is a sensitizer
2. Classification: Acceptable

Procedure (Deviation From §81-6): none

Results:

Table IV (cont.)

Closed-Patch Repeated Insult Dermal Sensitization Study
of Manufacturing Concentrate for 9309-Sandoz Water Based Fogger
in Guinea Pigs

Individual Dermal Scores at Challenge (cont.)^a
Group: II
Material: Manufacturing Concentrate for 9309-Sandoz Water Based Fogger
Induction Concentration: 100%
Challenge Concentration: 25%

Group IIA					
Animals Treated During Induction					
Animal No. and Sex	Interval		Animal No. and Sex	Interval	
	24 Hrs	48 Hrs		24 Hrs	48 Hrs
0223 M	0.5	0.5	0329 F	0.5	0.5
0224 M	0.5	0.5	0330 F	0.5	0.5
0225 M	1	1	0331 F	0.5	0.5
0226 M	1	1	0332 F	1	0.5
0227 M	1	1	0333 F	1	1
0228 M	0.5	0.5	0334 F	2	2
0229 M	0.5	0.5	0335 F	0.5	0.5
0230 M	1	1	0336 F	0.5	0.5
0231 M	1	1	0337 F	0.5	0.5
0232 M	1	1	0338 F	1	1
Sum of Male and Female Scores:				16.0	15.5
Mean ^c :				0.8	0.8

^aScored using the scoring system presented in Appendix B.
^bMean-Severity Index.
M=Male; F=Female.

Table IV (cont.)

Closed-Patch Repeated Insult Dermal Sensitization Study
of Manufacturing Concentrate for 9309-Sandoz Water Based Fogger
in Guinea Pigs

Individual Dermal Scores at Challenge (cont.)^a
Group: II (cont.)
Material: Manufacturing Concentrate for 9309-Sandoz Water Based Fogger
Challenge Concentration: 25%

Group IIB					
Irritation Control Animals ^b					
Animal No. and Sex	Interval		Animal No. and Sex	Interval	
	24 Hrs	48 Hrs		24 Hrs	48 Hrs
0243 M	0.5	0	0349 F	0.5	0.5
0244 M	0	0	0350 F	1	0.5
0245 M	0.5	0.5	0351 F	0.5	0.5
0246 M	0	0.5	0352 F	0.5	0.5
0247 M	0.5	0.5	0353 F	0.5	0.5
Sum of Male and Female Scores:				4.5	4.0
Mean ^c :				0.4	0.4

^aScored using the scoring system presented in Appendix B.
^bIrritation control animals were treated at challenge only.
^cMean-Severity Index.
M=Male; F=Female.